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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,782	12/17/2001	Lex M. Cowsert	RTS-0343	6567

EXAMINER	
SCHULTZ, JAMES	

ART UNIT	PAPER NUMBER
1635	

7590 07/14/2004

Jane Massey Licata
Licata & Tyrrell, P.C.
66 East Main Street
Marlton, NJ 08053

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/023,782	COWSERT ET AL.	
	Examiner	Art Unit	
	J. Douglas Schultz, Ph.D.	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 4-20* is/are pending in the application.

4a) Of the above claim(s) *15-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 4-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/17/01; 6/20/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I in the reply filed on April 23, 2004 is acknowledged. The traversal is on the ground(s) that the two groupings in the restriction contain claims with the same elements or technical features, namely an antisense compound targeted to TFAP2C. Applicants also argue that the claims of Group II are dependent claims upon claim 1, and by law are related. Applicants finally argue that there would be no additional search burden if the restriction is not made, because applicants assert any search performed to identify art relating to a compound targeted to TFAP2C would also identify relevant art to any methods of inhibiting the expression of TFAP2C using such compounds.

These arguments are found partially persuasive. The persuasive element pertains to the fact that claim 1 links the inventions of Groups I and II. Accordingly, the restriction requirement is hereby amended. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is

withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The restriction is nevertheless considered proper, in view of the amendment above. While applicants argue that the two groupings in the restriction contain claims with the same elements or technical features, this is not the standard by which the propriety of a restriction is determined. Regardless of whether the Groups share a technical feature, MPEP § 806.05(h) indicates that compounds are distinct from their methods of use if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. In the instant case the product antisense oligos can be used as probes for identifying the presence of specific mRNA transcripts in *in situ* hybridization assays, which does not involve administering antisense oligos to cells, tissues, or whole animals as present in group II. Thus, while antisense oligos directed to TFAP2C is a technical feature that is shared in the two groups, restriction is nevertheless considered proper provided there is also a search burden placed upon the examiner to search both inventions in the same application.

Such a search burden is considered to exist, because a search for art against one Group would not necessarily reveal art against the other Group. For example, there are many potential prior art compounds that meet the structural requirements of the compound claims of Group I, but said art may be silent as to their capacity to inhibit the target, such as the probe antisense oligo described above, which meets all the structural requirements of the compound claims, but has not been tested as to inhibitory capacity. Accordingly, the searches are divergent and not co-extensive, and therefore constitute a burden to search in the same application.

The requirement is still deemed proper and is therefore made FINAL.

Claims 15-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on April 23, 2004.

Information Disclosure Statement

2. Two information disclosure statements (IDS) have been submitted in the instant application, one on the filing date of December 17, 2001, and the other on June 20, 2003. The submission of both IDS's is in compliance with the provisions of 37 CFR 1.97. Accordingly, both information disclosure statements have been considered by the examiner, and are included herewith.

Claim Rejections - 35 USC § 112

3. Claim 1 recites the limitation "said nucleic acid molecule encoding TFAP2C 1". There is insufficient antecedent basis for this limitation in the claim, because while a molecule encoding TFAP2C has been recited earlier in the claim, no prior reference to TFAP2C 1 has been provided in the claim. If it is applicants' intention to refer to the TFAP2C molecule, deletion of the "1" at the end of TFAP2C would obviate this rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 2, 4, 5, and 11-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Dillon *et al.* (WO 01/40269 A2).

The invention of the above claims is drawn to antisense compounds 8 to 50 nucleobases long that target TFAP2C of SEQ ID NO: 3 and inhibit TFAP2C, or said compounds comprising internucleoside linkages which may be phosphorothioate linkages, or compositions comprising said compounds and pharmaceutically acceptable diluents or colloidal dispersion systems thereof.

Dillon *et al.* teach an antisense compound 10 to 40 nucleobases long that targets the TFAP2C polynucleotide, and generally disclose antisense compounds targeted to same that comprise internucleoside linkages that may be phosphorothioate linkages, along with antisense compositions comprising pharmaceutically acceptable diluents and colloidal dispersion systems (i.e. liposomes) thereof.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 and 103 that form the basis for the rejections under these sections made in this Office action:

A person shall be entitled to a patent unless –

102(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

103(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1, 2, 11, 12, and 14 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Cook *et al.* (U. S. Patent Number 6,127,533).

The invention of the above claims is drawn to antisense compounds 8 to 50 nucleotides in length that specifically hybridize with TFAP2C of SEQ ID NO: 3 or its active sites and inhibits the expression of TFAP2C, or wherein said compound is in composition with a pharmaceutically acceptable diluent.

SEQ ID NO: 22 of Cook *et al.* possesses 100% identity with nucleobases 2786 to 2804 of the instant application, and would thus specifically hybridize with applicants instant TFAP2C target of SEQ ID NO: 3. Although this reference does not specifically teach the function of inhibiting TFAP2C as claimed in the present application, the above-listed compound of the prior art meets all the structural limitations as set forth in the instant claims. Because the sequence is substantially identical to applicant's claimed compounds, in the absence of evidence to the contrary the compound of the prior art is thus considered to possess the functional limitations of specifically hybridizing with and inhibiting the expression of TFAP2C. Support for this conclusion is drawn from MPEP 2112:

> Where applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim **but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a**

> **102/103 rejection**. "There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102." *In re Best*, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic. Therefore, a 35 U.S.C. 102/103 rejection is appropriate for these types of claims as well as for composition claims. *Emphasis supplied.*

In rejecting the claims of the above under 35 U.S.C. 102 and 103, a prima facie case has been established by the examiner whereby the burden of proof in showing that the claimed compounds are not anticipated by the compound of the prior art as stated lies with the applicant, as per MPEP 2112.01:

> Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433.

Furthermore, since the oligos of Cook *et al.* are disclosed in buffer diluents, and since such buffers are considered to be pharmaceutically acceptable, Cook *et al.* is considered to teach TFAP2C antisense compounds in composition with pharmaceutically acceptable diluents.

Thus, in the absence of evidence to the contrary, the antisense compounds of the above claims of the instant application are considered anticipated and/or obvious as outlined above.

6. Claims 1, 2, and 11 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Caskey *et al.* (U. S. Patent Number 5,981,185).

The invention of the above claims is drawn to antisense compounds 8 to 50 nucleotides in length that specifically hybridize with TFAP2C of SEQ ID NO: 3 or its active sites and inhibits the expression of TFAP2C.

SEQ ID NO: 10 of Caskey *et al.* possesses 100% identity with nucleobases 2166 to 2186 of the instant application, and would thus specifically hybridize with applicants instant TFAP2C target of SEQ ID NO: 3. Although this reference does not specifically teach the function of inhibiting TFAP2C as claimed in the present application, the above-listed compound of the prior art meets all the structural limitations as set forth in the instant claims. Because the sequence is substantially identical to applicant's claimed compounds, in the absence of evidence to the contrary the compound of the prior art is thus considered to possess the functional limitations of specifically hybridizing with and inhibiting the expression of TFAP2C. Support for this conclusion is drawn from MPEP 2112:

> Where applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim **but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection**. "There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102." *In re Best*, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic. Therefore, a 35 U.S.C. 102/103 rejection is appropriate for these types of claims as well as for composition claims. *Emphasis supplied.*

In rejecting the claims of the above under 35 U.S.C. 102 and 103, a prima facie case has been established by the examiner whereby the burden of proof in showing that the claimed compounds are not anticipated by the compound of the prior art as stated lies with the applicant, as per MPEP 2112.01:

> Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the

> same, the applicant has the burden of showing that they are not. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433.

Thus, in the absence of evidence to the contrary, the antisense compounds of the above claims of the instant application are considered anticipated and/or obvious as outlined above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1, 2, and 4-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dillon *et al.*, Takahashi *et al.* (Biochem. Biophys. Res. Comm. 2000. 278:719-793), McPherson *et al.* (Proc. Natl. Acad. Sci. USA 1997. 94:4342-4347), Taylor *et al.* (Drug Disc. Today, 1999.

4(12)562-567), Baracchini *et al.* (U. S. Patent Number 5,801,154) and Bennett (U. S. Patent Number 5,998,148).

The invention of the above claims is drawn to antisense compounds 8 to 50 nucleobases long that target TFAP2C of SEQ ID NO: 3, or said compounds comprising internucleoside linkages which may be phosphorothioate linkages, nucleobase modifications which may be 5-methylcytosine modifications, and 2' modifications which may be 2'-O-methoxyethyl modifications, chimeras, or compositions comprising said compounds and pharmaceutically acceptable diluents or colloidal dispersion systems thereof.

Dillon *et al.* teach an antisense compound 10 to 40 nucleobases long that targets the TFAP2C polynucleotide, and generally disclose antisense compounds targeted to same that comprise internucleoside linkages that may be phosphorothioate linkages, along with antisense compositions comprising pharmaceutically acceptable diluents and colloidal dispersion systems (i.e. liposomes) thereof. Dillon *et al.* do not teach sugar (e.g. 2'-O-methoxyethyl sugars) or nucleobase (e.g. 5-methylcytosine) modified antisense compounds.

Takahashi *et al.* teach an antisense compound that targets TFAP2C and inhibit its expression.

McPherson *et al.* teach the cDNA sequence encoding TFAP2C of SEQ ID NO: 3. McPherson *et al.* does not teach antisense sequences comprising internucleoside, nucleobase, and 2' modifications, chimeras, or compositions comprising said compounds and pharmaceutically acceptable diluents or delivery systems thereof.

Taylor et al. teach that antisense oligonucleotides 7-30 nucleotides long can be synthesized to inhibit the expression of any protein provided the cDNA sequence is known.

Taylor *et al.* also indicate that the knowledge for making and using such oligos is available to those of ordinary skill in the art, that it is common practice to chemically modify the such oligonucleotides to prolong their bioactivity, and also teach that with software analysis and high affinity oligos, one needs to screen only 3-6 oligos to find one that inhibits its target 66-95% (p. 565).

Baracchini *et al.* teach that antisense oligonucleotides can be used for research purposes, and also teach that preferred antisense oligonucleotides are modified in their sugar, backbone linkage and nucleobase composition (col. 6). Baracchini teaches that such modifications are desirable in antisense oligos because these modifications have desirable properties such as enhanced cellular uptake, enhanced affinity for nucleic acid targets and increased stability in the presence of nucleases. Baracchini et al provide specific embodiments of such modifications at columns 6-8 and in Example 1. These specific examples taught by Baracchini *et al.* include the presently claimed phosphorothioate linkages, 2'-O-methoxyethyl sugars, 5-methylcytosine and chimeric oligonucleotides. Tables 1-4 show the successful design and use of modified oligonucleotides in cells in culture. Table 1 exemplifies the successful practice of general antisense design taught at columns 8-10. Column 4 teaches various carriers for antisense delivery. Baracchini *et al.* also teaches at column 8 that antisense oligonucleotides are preferably 8 to 30 nucleotides and that it is more preferable to make antisense oligonucleotides that are 12 to 25 nucleotides in length. Baracchini is considered to comprise a detailed blueprint for how to make and use inhibitory antisense oligos to target any known gene.

Bennett *et al.* is considered to parallel the teachings of Baracchini *et al.* Bennett *et al.* teaches general antisense targeting guidelines at columns 3-4. Bennett *et al.* also teaches

targeting 5'-untranslated regions, start codons, coding regions, and 3'-untranslated regions of a desired target. Bennett teaches, in column 5, for example, that antisense compounds are commonly used as research reagents and diagnostics. Column 5 indicates that antisense oligonucleotides 8-30 nucleotides in length are particularly preferred. Columns 6-7 teach that preferred antisense oligonucleotides contain modified internucleoside linkages including phosphorothioate linkages, among others. Columns 7-8 teach that preferred antisense oligonucleotides comprise modified sugar moieties including 2'-O-methoxyethyl. Bennett *et al.* also teach one of ordinary skill to modify nucleobases in antisense oligonucleotides, including the teaching of 5-methylcytosine (col. 8-9), and also to use chimeric antisense oligonucleotides (col. 9-10). Bennett *et al.* teach that the above modifications are known in the art to provide beneficial attributes to antisense oligonucleotides such as increased hybridization and nuclease protection, for example. Columns 10-24 teach numerous "carriers" for antisense oligonucleotides. Table 1 teaches the successful targeting of those regions taught in columns 3-4 with chimeric phosphorothioate oligonucleotides having 2'-MOE (a 2'-O-methoxyethyl modification). Thus, Bennett *et al.* is also considered to comprise a detailed blueprint for how to make and use inhibitory antisense oligos to target any known gene.

It would have been obvious to one of ordinary skill in the art to use the cDNA sequence of McPherson to develop antisense sequences as taught by both Dillon *et al.* and Takahashi *et al.* It would also have been obvious to modify such antisense sequences using the instantly claimed modifications as taught by Taylor, Baracchini, and Bennett for inhibition of TFAP2C expression.

One would have been motivated to create such compounds because Dillon *et al.* and Takahashi *et al.* provide express motivation by teaching antisense compounds that target and

hybridize to TFAP2C. One would have been motivated to further modify such antisense compounds, because Dillon expressly recognized the importance of phosphorothioate-modifying such oligos to prolong bioactivity, and further because Taylor *et al.*, Baracchini *et al.* and Bennett *et al.,* all teach that such the specific modifications claimed instantly (i.e. 2'-O-methoxyethyl and 5-methylcytosine modifications) increase an antisense compound's cellular uptake, target affinity and resistance to degradation.

Finally, one would have a reasonable expectation of success in making such oligos given that the chemistry for making said oligos is taught in detail by both Baracchini *et al.* and Bennett *et al.*, and because such steps are routine to those of ordinary skill in the art. Furthermore, one would have a reasonable expectation of success in finding oligos that achieve significant inhibition because Taylor teaches that with software analysis and high affinity oligos, one needs to screen only 3-6 oligos to find one that inhibits its target 66-95%, and since both both Baracchini *et al.* and Bennett *et al.* teach detailed protocols of screening and using modified antisense compounds targeted to distinct regions of a target gene.

Thus in the absence of evidence to the contrary, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz, Ph.D. whose telephone number is 571-272-0763. The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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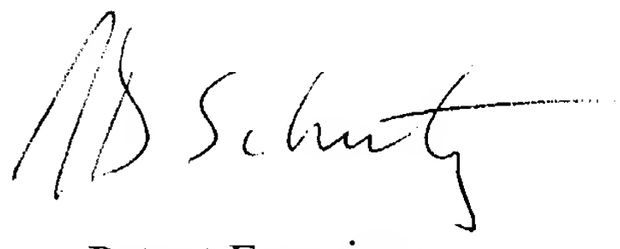
JD Schultz, PhD



Patent Examiner
Art Unit 1635